Point of care testing in microbiology
POCT在微生物學中的應用

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The primary goal of the clinical microbiology laboratory is to provide an aetiological diagnosis for patients suffering from infections and guide the management of infections by performing antimicrobial susceptibility testing. In many laboratories, the conventional approach of microscopy, culture, and serology continues to be the mainstay procedures. Culture-based techniques of microbial detection suffers from the major limitation of a long turnaround time. Time is required for the initial processing of specimens, followed by in vitro growth of microbes, identification using phenotypic tests, and time for antimicrobial susceptibility assay. These procedures, unlike other specialties of laboratory medicine, are labour-intensive and require highly trained laboratory staff.

In recent years, many non-culture-dependent methods of microbial identification and automated instrumentations are available nowadays, and some laboratories have started to adopt molecular techniques for the detection of microbial pathogens, primarily using nucleic acid amplification methods such as the polymerase chain reaction. These tests, however, are not yet widely available and turnaround time is still a limitation owing to the need for transporting the specimens to the laboratory, time required for processing of the specimens, and infrequently testing.

Apart from a relatively long turnaround time, access to a good microbiology laboratory service is another concern for clinicians. With the expanding role of primary care and movement towards ambulatory care in medicine, more and more patients are receiving care in primary care facilities, day centres, and outpatient clinics. Under such circumstances, the traditional microbiology laboratory service may not be able to give reports that have immediate impact on patient care and management. Technological advances now permit some tests to be performed in these settings with results available within a short period of time.

Point of care testing (POCT), also known as near patient testing (NPT), addresses the problem of a long turnaround time encountered in different branches of laboratory medicine hence may theoretically improve the quality of patient care. NPT has been defined as "the analytical testing of clinical specimens beyond the confines of the laboratory" or simply "the provision of laboratory testing at the point where patient care is rendered".

The concept of NPT is not a new one. Microscopy has been used for many years in gynaecological wards and clinics as well as sexually transmitted disease clinics for the rapid diagnosis of gonorrhoea, Trichomonas vaginalis and yeast infection, and bacterial vaginosis. Simple dipstick

urinalysis is used in general wards and clinics for a presumptive diagnosis of urinary tract infection. In recent years, NPT benefits from development of immunochromogenic assays and molecular biology. Rapid disposable immunoassay-based tests are most popular in NPT, understandably because of the ease of performing the tests. Some systems also use nucleic acid probes for the rapid detection of pathogens in clinical specimens.

Benefits of NPT

Decreased test turnaround time can potentially provide important clinical benefits. More timely test results that more closely approximate the patient's current condition permit clinicians to make evidenced-based medical decisions. This optimizes therapeutic decisions and provides for the mmediate treatment of patients with abnormal esults and the patient's disposition. Decreased ırnaround time also minimizes additional, ınecessary laboratory investigations and contributes a concomitant reduction in unnecessary empirical dications administered to patients while they are iiting laboratory test results. This testing also provide benefits deemed important from the ent's perspective, including reduced waiting greater convenience, and immediate treatment essary.

available

tion to urinalysis test strips that have been ble for many years, a number of assay-based tests are available nowadays. es include tests for hepatitis B, HIV, , adenovirus, herpesvirus, influenza A, ry syncytial virus, Epstein-Barr virus, elicobacter pylori, Streptococcus pyogenes, ı, Plasmodium falciparum, etc. Without e will appear on the market in the ars. These assays detect either the antibodies of the respective microbes in clinical specimens. The specimens are gener. obtained in a non-invasive manner. Examp include capillary blood, respiratory tract specime (e.g. a throat swab), faeces, and even saliva.

These test kits come complete with instructions fc use and all the instruments, reagents, and control necessary for the test. Using the kits is usually straight forward and training of personnel carrying out the tests is minimal. Preparation of specimen is minimal or even not required; for example blood tests generally utilize whole blood rather than serum or plasma so that centrifugation is not necessary.

Considerations when utilizing NPT

Despite all the favourable characteristics, the followings need to be taken into consideration when NPT is to be incorporated into everyday patient care.

Test limitations

Though the tests markets are stated to have sensitivity and specificities, care need to be exercised in the interpretation of the results. This is especially true when interpreting antibody tests. The presence of antibody in the blood against a certain pathogen does not mean that the patient is having active infection. One example is the detection of antibodies against Helicobacter pylori in whole blood samples. After successful eradication of the organism, antibodies tend to persist in the body for months. Hence a positive antibody test must be interpreted in the light of other clinical and laboratory findings, and more invasive or specific tests may have to be performed if clinically indicated.

Cost

One of the prime attractions of NPT is that these tests save costs in terms of a more rapid turnaround time and reduces the need for additional laboratory

testing and empirical antimicrobial therapy. However, there are few data on the cost effectiveness of NPT in primary care. Investigations performed in NPT are sometimes duplicated in the laboratory, more so in hospital settings. NPT should help to reduce over-investigation, but their convenience can sometimes mean more tests are done.

Whether NPT saves cost in patient management need to be carefully evaluated. Hidden costs include space, capital equipment investment, and maintenance of equipment. NPT is a low volume activity with relatively few tests being performed. This results in relative inefficiencies in staffing and use of kits, consumables, and specimen handling time. The cost of controls is high and the kit may have a short shelf life. This is especially important for tests which might be performed infrequently, and such wastage can increase the cost of NPT considerably.

Where should NPT be performed?

The main market for NPT is the primary care setting where access to laboratory service may not be readily available. Other potential uses include the hospital wards when a 24-hour laboratory service is not available, outpatient clinics and the accidents and emergency department where a definitive diagnosis need to be made to facilitate disposition and treatment of patients. Regardless of the location of the testing site, one must ensure that the environment is safe, clean, appropriate to the task, and managed by well-trained staff.

Provision of tests and role of the laboratory

Who should do the tests in NPT - the medical practitioner, nurse, or a qualified technician? Whoever is performing the tests, adequate training of personnel is essential to ensure the accuracy and reproducibility of the test. Proper collection of specimens in the required volume, handling and operation of instruments and equipment, timing for addition of reagents and reading of results, and safety in the testing environment with respect to the handling of sharps and body fluids are some key issues in the training of the personnel. Apart from ensuring the delivery of accurate results, proper training of testing personnel is also crucial from a medicolegal point of view, especially in testing for HIV and sexually transmitted diseases.

Near patient testers must be properly trained by clinical laboratory staff or commercial supplier. Not only should the tester be competent in carrying out the test procedures, he or she must be competent in the collection of clinical specimens since a poor specimen quality or quantity will nullify all subsequent procedures. Competence of the staff must be check and certified with periodic verification and/or re-training to ensure continuing competence.

Microbiology laboratories have an important role in the provision and supporting NPT. This offers the laboratories an opportunity to take the initiative to find out what clinicians want and to help them to select the most appropriate tests. The laboratories can also assist the practitioner in training of testing personnel, drafting standard operating procedures, monitoring external quality assurance and internal quality control, as well as choice and maintenance of equipment.

If NPT means fewer tests are to be performed by the laboratory, there is a risk that information currently collected by clinical laboratories for surveillance purposes may be lost or rendered incomplete. Examples include antimicrobial resistance patterns and prevalent organisms causing infections in the community. Information on these areas is important in guiding treatment and studying